REMARKS

Claims 1-25 and 33 have been cancelled. Claims 26-32 and 34 have been amended. New claim 35 is added. Claims 26-32 and 34-35 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Status of claims

It is noted that the Examiner has not applied the art rejections, pending resolution of issues under 35 U.S.C. § 112, first and second paragraphs.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 26-31 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that it is not clear whether contacting cells with a solution of telomerase inhibitor is meant to be under *in vitro* or *in vivo* conditions.

In response, the telomerase inhibitor of the presently claimed invention is effective both in vitro and in vivo. As set forth in the Office Action of March 12, 2003, based upon the evidence of Figure 4 which shows marked inhibition of intracellular telomerase activity, the skilled art worker would understand that inhibition of the telomerase activity of the cells may be either in vivo or in vitro. In addition, it has been reported recently that a continuous administration of EGCG (up to 1.2mg/mouse/day) specifically inhibited in vivo growth of a telomerase-dependent tumor (see Cancer Res. vol. 63: pages 824-830, 2003 submitted as Attachment A). This paper supports Applicants' position that EGCG is an effective in vivo agent.

Reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 30-31 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that it is not clear how varying concentration of catechins in the extract (claim 31) or in telomerase inhibitor (claim 30) yields one single final concentration, i.e., the claims recite a range of concentrations for catechins but the base claim is limited to 15 μM.

In response, claim 26 has been amended to recite a range of 5 to 15 μM. Support for the amendment is found in Example 2 and Figure 2. Example 2 at page 10 of the present specification describes telomerase activity in reaction solutions of 8 different EGCG concentrations - from 0.1 μM to 20 μM. The data is shown in Figure 2 which clearly shows almost no activity (nearly complete inhibition) at three points within the claimed range - 5 μM, 10 μM, and 15 μM. Thus, the recitation of a concentration of EGCG of 5 to 15 μM is believed to be fully supported by the disclosure.

Claim 30 is consistent with claim 26 as claim 30 refers to the concentration of the catechins in the composition which is then adjusted to the 5 to 15 μM concentration as recited in claim 26.

Claim 31 has been amended for further clarity to recite that the green tea extract is a dried powder. Support for the amendment is on page 8, line 2 of the present specification. Again, the epigallocatechin gallate is prepared from the green tea extract to achieve a concentration within the range recited in claim 26.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 32-34 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that it is not clear which dosage results in an "effective amount" of catechins to result in a precise concentration of 15 μM.

In response, claim 26 has been amended to recite a range of 5 to 15 μM. Support for the amendment is found in Example 2 and Figure 2. Example 2 at page 10 of the present specification describes telomerase activity in reaction solutions of 8 different EGCG concentrations - from 0.1 μM to 20 μM. The data is shown in Figure 2 which clearly shows almost no activity (nearly complete inhibition) at three points within the claimed range - 5 μM, 10 μM, and 15 μM. Thus, the recitation of a concentration of EGCG of 5 to 15 μM is believed to be fully supported by the disclosure.

Clearly, "an effective amount" is an amount to provide a concentration in the range of 5 to 15 μM. Furthermore, the limitations of claim 33 have been incorporated into claim 26 to recite that a step of contacting cells exhibiting telomerase activity is achieved by topical administration or injection of a catechin composition. The catechin concentration is the same as the dosage when administration is topical or by injection or plaster (claim 34). That is, the cells are contacted directly with an amount of EGCG as specified in claim 26.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of all grounds of rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 28 is rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) has possession of the claimed invention at the time that the application was filed.

The Examiner states that there is no disclosure of catechins other than EGCG.

This ground of rejection is believed to be overcome by Applicants' amendment of claim 28. Claim 28 recites that the catechin composition comprises a combination of epigallocatechin gallate with a catechin selected from the group consisting of epigallocatechin, epicatechin gallate, and epicatechin. Thus, EGCG is always a component of the catechin composition although other catechins may be present. Support for inclusion of other catechins is found in Figure 1, for example, which shows that other catechins besides EGCG have telomerase inhibiting activity although EGCG produced the strongest inhibition.

Furthermore, new claim 35 is added which is limited to EGCG at a concentration of 5 to 15 μM.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 26-30 are rejected under 35 U.S.C. § 112, first paragraph because the specification, while being enabling for the use of EGCG at a concentration of 15 μM, does not reasonably provide enablement for use of other catechins or use of crude green tea extract.

In response, as discussed above, the claims are now limited to where EGCG is present at a concentration of 5 to 15 μM. Example 2 at page 10 of the present specification describes telomerase activity in reaction solutions of 8 different EGCG concentrations - from 0.1 μM to 20 μM. The data is shown in Figure 2 which clearly shows almost no activity (nearly complete inhibition) at three points within the claimed range - 5 μM, 10 μM, and 15 μM. Thus, the recitation of a concentration of EGCG of 5 to 15 μM is believed to be fully supported by the disclosure.

Thus, although the composition may include other components, EGCG, for which the Examiner has indicated that claims 26-30 are enabled, is always a component of the composition.

In view of Applicants' amendments, withdrawal of the above ground of rejection is respectfully requested.

Claims 27 and 31 are rejected under 35 U.S.C. § 112, first paragraph as the specification does not provide guidance or working examples on achieving the precise concentration of 15 μM.

In response, the claims have been amended to recite a range of EGCG of 5 to 15 μM as discussed above. It is respectfully submitted that one skilled in the art could arrive at a concentration of EGCG within this range. Furthermore, the specification at page 10 describes a tea catechin extract (THEA-FLAN 90S) and also describes the concentration of the tea catechin extract with respect to polyphenols and specifically (-)-Epigallocatechin gallate (50% by weight) and (-)-Epigallocatechin. Clearly it was within the skill level in the art to determine the catechin concentrations in a tea or other extract.

The Examiner may be misinterpreting statements made in discussion of the art rejections with the Amendment of March 12, 2003. While it was not straightforward to determine the composition of the catechin extract based upon the information given in the disclosure of JP910108977 because of insufficient information, one skilled in the art can determine the catechin composition of a green tea extract as illustrated in Example 3 of the specification, discussed above.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 32-34 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) has possession of the claimed invention at the time that the application was filed.

The Examiner states that there is no disclosure that epigallocatechin gallate or any other catechin inhibits telomerase in vivo at a concentration of 15 μM.

In response, the present claims have now been amended to recite a range of 5 to 15 μM as discussed above. It is clear from the specification (e.g. Example 4) that telomerase activity of cells can be inhibited by contacting the cells with an EGCG solution in this concentration range, whether in vivo or in vitro. As set forth in the Office Action of March 12, 2003, based upon the evidence of Figure 4 which demonstrates marked inhibition of intracellular telomerase activity, the skilled art worker would understand that inhibition of the telomerase activity of the cells may be either in vivo or in vitro. The low concentration of 5-15 μM is clearly supported by the present specification and drawings. In addition, it has been reported recently that a continuous administration of EGCG (up to 1.2mg/mouse/day) specifically inhibited in vivo growth of a telomerase-dependent tumor (see Cancer Res. vol. 63: pages 824-830, 2003 submitted as Attachment A). This paper supports Applicants' position that EGCG is an effective in vivo agent.

Furthermore, the limitations of claim 33 have been incorporated into claim 26 to recite that a step of contacting cells exhibiting telomerase activity is achieved by topical administration or injection of a catechin composition, the catechin concentration is the same as the dosage when administration is topical or by injection or plaster (claim 34). That is, the cells are contacted directly with an amount of EGCG as specified in claim 26.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Claims 32-34 are rejected under 35 U.S.C. § 112, first paragraph as based upon a non-enabling disclosure.

The Examiner states that the specification does not teach how to achieve a concentration of 15 μM in vivo. In response, the present claims have now been amended to recite a range of 5 to 15 μM as discussed above and the limitations of claim 33 have been incorporated into claim

26 to recite that a step of contacting cells exhibiting telomerase activity is achieved by topical administration or injection of a catechin composition. The catechin concentration is the same as the dosage when administration is topical or by injection (claim 26) or plaster (claim 34). That is, the cells are contacted directly with an amount of EGCG as specified in claim 26.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

CONCLUSION

Applicants respectfully request a prompt examination of the present application with respect to the prior art. Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 18, 2003

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